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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/729,146  | 12/04/2003  | Timothy A. Ringeisen | KN P 0146             | 1356             |
| 42016   | 7590        | 06/22/2007           | EXAMINER              |                  |
| KENSEY NASH CORPORATION<br>735 PENNSYLVANIA AVENUE<br>EXTON, PA 19341 |             |                      | ROGERS, JAMES WILLIAM |                  |
| ART UNIT  |             | PAPER NUMBER         |                       |                  |
|   |             | 1618                 |                       |                  |
| MAIL DATE   |             | DELIVERY MODE        |                       |                  |
| 06/22/2007  |             | PAPER                |                       |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

|  |                                      |
|--|--------------------------------------|
| Application No.<br><br>10/729,146      | Applicant(s)<br><br>RINGEISEN ET AL. |
| Examiner<br><br>James W. Rogers, Ph.D. | Art Unit<br><br>1618                 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 May 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1.  The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

**3**

a)  The period for reply expires 6 months from the mailing date of the final rejection.  
 b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2.  The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3.  The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

- (a)  They raise new issues that would require further consideration and/or search (see NOTE below);
- (b)  They raise the issue of new matter (see NOTE below);
- (c)  They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d)  They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4.  The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7.  For purposes of appeal, the proposed amendment(s): a)  will not be entered, or b)  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8.  The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9.  The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10.  The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11.  The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12.  Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.

13.  Other: \_\_\_\_\_.

Continuation of 11. does NOT place the application in condition for allowance because:

In the arguments filed 5/29/2007 applicants once again assert that their application is allowable over the cited art because the alignment of the fibers in Stone and Li do not align themselves in the form of layers or plates and this is substantiated by the new declaration by the inventor which details how the processes above are different than in the claimed invention. Applicants also asserted that they only commented on the respective processes in order to explain why the articles were distinct.

The relevance of these assertions is unclear, it is noted that the declaration by a coinventor is an opinion declaration, which does not include any working examples. While the declaration has been fully considered it does not place the application in condition for allowance. The declaration purports to show the differences between the method to produce the implants, as outlined previously the claims are not drawn to a method to produce polymeric implants but to the implants themselves. Since we are discussing the claimed product we must compare the implants described in the art with applicants claimed invention. The limitations that the implants comprise fibers, which are at least partially aligned in layers and plates, is simply not found very limiting by the examiner. Since the cited Stone and Li references describe implantable fibers, which are produced by compressing it is inherent that the fibers must at the very least form some layers (one fiber laying atop another fiber at least partially) of at least some of the fibers when they are compressed. Also at least Li states that the orientation of the fibers is in one direction, thus meeting the limitation of at least partial alignment.

Applicants further asserted that because of the statement in the prior action that the compression processes never feature a rotation of a piston or mold this precludes this possibility.

The relevance of this assertion is unclear since applicants claims do not preclude the use of a rotating piston or mold any method to make a polymer implant that meets applicants claimed product will meet the claim limitation. Applicants cannot exclude other processes to make polymer implants just because of comments within their remarks/arguments, it must be explicitly excluded from the claims, however the claims are drawn to a product therefore the method to produce the product is of little relevance as long as the claimed product is met by the prior art.

In the remarks filed 06/01/2007 Applicant's wish to make of record that the previous arguments/remarks filed on 04/26/2007 had an inadvertent mistake. The applicants replied in the arguments filed 04/26/2007 that the step of compression does not feature a rotating element to help align the fiber, this statement was said to have maybe went to far and could have given rise to a misunderstanding or misinterpretation. The misunderstanding could have arised because as in figure 4 of the application the apparatus features a rotating component. Applicants contend that this mistake was inadvertent and want the clarification presented to be entered and made of record. The examiner will enter this clarification into the record. Applicants lastly state that their invention is patentable over the cited art due to the reasons expressed in the after final remarks/arguments filed 04/26/2007 and argues that because the references impart a rotation to the slurry this would prevent alignment of the fibers. The examiner already commented on why the invention is not patentable over the prior art in the advisory action dated 05/11/2007 and in the remarks above, which is incorporated herein.



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